(b) bringing the delivery formulation into contact with the mucosal surface of the buccal cavity under conditions suitable to permit an effective amount of the peptide to be absorbed.

3. (Once Amended) The method of claim [2] 1 wherein the quaternary ammonium salt comprises benzalkonium chloride.

7. (Once Amended) A delivery system comprising [an aerosol] a dispenser containing a delivery formulation comprising an effective amount of an inactivated bioactive peptide and an effective amount of a mucosal absorption enhancer comprising a quaternary ammonium salt for enhancing mucosal absorption of the peptide in the buccal cavity.

8. (Once Amended) The system of claim 7 wherein the [delivery device] dispenser is selected from the group consisting of aerosol and non-aerosol dispensers.

9. (Once Amended) A medicament delivery formulation comprising an effective amount of an inactivated bioactive peptide and an effective amount of a mucosal absorption enhancer comprising a quaternary ammonium salt for enhancing mucosal absorption of the peptide in the buccal cavity.

Add new claims 11- 69 as follows:

11. (new) The method of claim 1 wherein the peptide has a molecular weight of at least 500 daltons.

12. (new) The method of claim 1 wherein the quaternary ammonium salt comprises a tetrasubstituted ammonium salt, in which the substituent groups comprise hydrocarbon compounds attached to the nitrogen by N-C bonds.

13 (new) The method of claim 1 wherein the quaternary ammonium salt is used at a final

concentration of between about 0.001 % and about 0.1 % based on the weight of the formulation.

14. (new) The method of claim 13 wherein the quaternary ammonium salt is used at a final concentration of about 0.005 % and about 0.05 %, based on the weight of the formulation.

15. (new) The method of claim 1 wherein the bioactive peptide is inactivated by a method comprising the steps of treating the peptide with ozone under conditions suitable to oxidize any disulfide bonds in order to form corresponding pairs of cysteic acid residues, and then stabilizing the resultant cysteic acid residues and preventing the reformation of disulfide bonds.

16. (new) The method of claim 15 wherein the inactivated bioactive peptide retains one or more properties selected from the group consisting of immunogenicity and anti-viral activity.

17. (new) The method of claim 1 wherein the bioactive peptide is selected from the group consisting of toxins affecting the presynaptic neurojunction, toxins affecting the postsynaptic neurojunction, toxins affecting ion channels, and toxins that damage the cell membrane.

18. (new) The method of claim 17 wherein the toxins affecting the presynaptic neurojunction toxins are selected from the group consisting of notexin, ß-bungarotoxin, crotoxin, taipoxin, textilotoxin and α-latrotoxin.

19. (new) The method of claim 17 wherein the toxins affecting the postsynaptic neurojunction are selected from the group consisting of α-conotoxins, α-cobrotoxin, erabutoxin, α-cobratoxin and α-bungarotoxin.

20. (new) The method of claim 17 wherein the toxins affecting ion channels are selected from the group consisting of dendrotoxins, scorpion toxins, m-conotoxins, and sea anemone toxins.

21. (new) The method of claim 17 wherein the toxins that damage the cell membrane are membrane-damaging toxins selected from the group consisting of myotoxins, cardiotoxins, mellitin, and phospholipases.

22. (new) The method of claim 16 wherein the bioactive peptide is selected from the group consisting of protein hormones and enzymes.

23. (new) The method of claim 22 wherein the bioactive peptide is a protein hormone selected from the group consisting of oxytocin, arginine vasopressin, insulin, growth hormone and calcitonin.

24. (new) The method of claim 22 wherein the bioactive peptide is an enzyme selected from the group consisting of ribonuclease, lysozyme, chymotrypsin, trypsin, elastase, and papain.

25. (new) The method of claim 1 wherein the peptide is prepared by a method comprising the step of preparing a cDNA strand encoding the peptide.

26. (new) The method of claim 25 wherein the peptide is prepared by expressing the cDNA under conditions in which the peptide is recovered in an inactive form due to the failure to form one or more disulfide bridges.

27. (new) A medicament delivery method comprising;

(a) providing a delivery system comprising a delivery formulation comprising an effective amount of an inactivated bioactive macromolecule and an effective amount of a mucosal absorption enhancer comprising a quaternary ammonium salt for enhancing mucosal absorption of the peptide;

(b) bringing the delivery formulation into contact with the mucosal surface under conditions suitable to permit an effective amount of the peptide to be absorbed.

28. (new) The method of claim 27 wherein the bioactive macromolecule comprises a bioactive peptide having a molecular weight of at least 500 daltons, the quaternary ammonium salt comprises benzalkonium chloride at a final concentration of between about 0.001 % and about 0.1 % based on the weight of the formulation, the bioactive peptide a) has been inactivated by a method comprising the steps of treating the peptide with ozone under conditions suitable to oxidize any disulfide bonds in order to form corresponding pairs of cysteic acid residues, and then stabilizing the resultant cysteic acid residues and preventing the reformation of disulfide bonds, and b) is selected from the group consisting of toxins affecting the presynaptic neurojunction, toxins affecting the postsynaptic neurojunction, toxins affecting ion channels, and toxins that damage the cell membrane.

29. (new) The method of claim 28 wherein the benzalkonium chloride is used at a final concentration of about 0.005 % and about 0.05 %, based on the weight of the formulation, the inactivated bioactive peptide retains one or more properties selected from the group consisting of immunogenicity and anti-viral activity, and the bioactive peptide comprises a toxin affecting the postsynaptic neurojunction and is selected from the group consisting of α-conotoxins, α-cobrotoxin, erabutoxin, α-cobratoxin and α-bungarotoxin.

30. (new) The system of claim 7 wherein the quaternary ammonium salt comprises benzalkonium chloride.

31. (new) The system of claim 7 wherein the peptide has a molecular weight of at least 500 daltons.

32. (new) The system of claim 7 wherein the quaternary ammonium salt comprises a tetrasubstituted ammonium salt, in which the substituent groups comprise hydrocarbon

compounds attached to the nitrogen by an N-C bond and are selected from substituted and unsubstituted, saturated and unsaturated, aliphatic and aromatic, branched and normal chain groups.

33. (new) The system of claim 7 wherein the quaternary ammonium salt is used at a final concentration of between about 0.001 % and about 0.1 % based on the weight of the formulation.

34. (new) The system of claim 33 wherein the quaternary ammonium salt is used at a final concentration of about 0.005 % and about 0.05 %, based on the weight of the formulation.

35. (new) The system of claim 7 wherein the bioactive peptide is inactivated by a method comprising the steps of treating the peptide with ozone under conditions suitable to oxidize any disulfide bonds in order to form corresponding pairs of cysteic acid residues, and then stabilizing the resultant cysteic acid residues and preventing the reformation of disulfide bonds.

36. (new) The system of claim 35 wherein the inactivated bioactive peptide retains one or more properties selected from the group consisting of immunogenicity and anti-viral activity.

37. (new) The system of claims 7 wherein the bioactive peptide is selected from the group consisting of toxins affecting the presynaptic neurojunction, toxins affecting the postsynaptic neurojunction, toxins affecting ion channels, and toxins that damage the cell membrane.

38. (new) The system of claim 37 wherein the toxins affecting the presynaptic neurojunction toxins are selected from the group consisting of notexin, ß-bungarotoxin, crotoxin, taipoxin, textilotoxin and α-latrotoxin.

39. (new) The system of claim 37 wherein the toxins affecting the postsynaptic neurojunction are selected from the group consisting of α-conotoxins, α-cobrotoxin, erabutoxin, α-cobratoxin and α-bungarotoxin.

40. (new) The system of claim 37 wherein the toxins affecting ion channels are selected from the group consisting of dendrotoxins, scorpion toxins, m-conotoxins, and sea anemone toxins.

41. (new) The system of claim 37 wherein the toxins that damage the cell membrane are membrane-damaging toxins selected from the group consisting of myotoxins, cardiotoxins, mellitin, and phospholipases.

42. (new) The system of claim 36 wherein the bioactive peptide is selected from the group consisting of protein hormones and enzymes.

43. (new) The system of claims 37 wherein the bioactive peptide is a protein hormone selected from the group consisting of oxytocin, arginine vasopressin, insulin, growth hormone and calcitonin.

44. (new) The system of claim 42 wherein the bioactive peptide is an enzyme selected from the group consisting of ribonuclease, lysozyme, chymotrypsin, trypsin, elastase, and papain.

45. (new) The system of claim 7 wherein the peptide is prepared by a method comprising the step of preparing a cDNA strand encoding the peptide.

46. (new) The system of claim 45 wherein the peptide is prepared by expressing the cDNA under conditions in which the peptide is recovered in an inactive form due to the failure to form one or more disulfide bridges.

47. (new) A delivery system comprising a dispenser containing a delivery system containing a delivery formulation comprising an effective amount of an inactivated bioactive

macromolecule and an effective amount of a mucosal absorption enhancer comprising a quaternary ammonium salt for enhancing mucosal absorption of the peptide.

48. (new) The system of claim 47 wherein the bioactive macromolecule comprises a bioactive peptide having a molecular weight of at least 500 daltons, the quaternary ammonium salt comprises benzalkonium chloride at a final concentration of between about 0.001 % and about 0.1 % based on the weight of the formulation, the bioactive peptide a) has been inactivated by a method comprising the steps of treating the peptide with ozone under conditions suitable to oxidize any disulfide bonds in order to form corresponding pairs of cysteic acid residues, and then stabilizing the resultant cysteic acid residues and preventing the reformation of disulfide bonds, and b) is selected from the group consisting of toxins affecting the presynaptic neurojunction, toxins affecting the postsynaptic neurojunction, toxins affecting ion channels, and toxins that damage the cell membrane.

49. (new) The system of claim 48 wherein the benzalkonium chloride is used at a final concentration of about 0.005 % and about 0.05 %, based on the weight of the formulation, the inactivated bioactive peptide retains one or more properties selected from the group consisting of immunogenicity and anti-viral activity, and the bioactive peptide comprises a toxin affecting the postsynaptic neurojunction and is selected from the group consisting of α-conotoxins, α-cobrotoxin, erabutoxin, α-cobratoxin and α-bungarotoxin.

50. (new) The formulation of claim 9 wherein the quaternary ammonium salt comprises benzalkonium chloride.

51. (new) The formulation of claim 9 wherein the formulation is adapted to be delivered by spraying to the roof of the mouth.

52. (new) The formulation of claim 9 wherein the quaternary ammonium salt comprises a tetrasubstituted ammonium salt, in which the substituent groups comprise

hydrocarbon compounds attached to the nitrogen by an N-C bond and are selected from substituted and unsubstituted, saturated and unsaturated, aliphatic and aromatic, branched and normal chain groups.

53. (new) The formulation of claim 9 wherein the quaternary ammonium salt is used at a final concentration of between about 0.001 % and about 0.1 % based on the weight of the formulation.

54. (new) The formulation of claim 53 wherein the quaternary ammonium salt is used at a final concentration of about 0.005 % and about 0.05 %, based on the weight of the formulation.

55. (new) The formulation of claim 9 wherein the bioactive peptide is inactivated by a method comprising the steps of treating the peptide with ozone under conditions suitable to oxidize any disulfide bonds in order to form corresponding pairs of cysteic acid residues, and then stabilizing the resultant cysteic acid residues and preventing the reformation of disulfide bonds.

56. (new) The formulation of claim 55 wherein the inactivated bioactive peptide retains one or more properties selected from the group consisting of immunogenicity and anti-viral activity.

57. (new) The formulation of claims 9 wherein the bioactive peptide is selected from the group consisting of toxins affecting the presynaptic neurojunction, toxins affecting the postsynaptic neurojunction, toxins affecting ion channels, and toxins that damage the cell membrane.

58. (new) The formulation of claim 57 wherein the toxins affecting the presynaptic neurojunction toxins are selected from the group consisting of notexin, ß-bungarotoxin, crotoxin, taipoxin, textilotoxin and α-latrotoxin.

59. (new) The formulation of claim 57 wherein the toxins affecting the postsynaptic neurojunction are selected from the group consisting of α-conotoxins, α-cobrotoxin, erabutoxin, α-cobratoxin and α-bungarotoxin.

60. (new) The formulation of claim 57 wherein the toxins affecting ion channels are selected from the group consisting of dendrotoxins, scorpion toxins, m-conotoxins, and sea anemone toxins.

61. (new) The formulation of claim 57 wherein the toxins that damage the cell membrane are membrane-damaging toxins selected from the group consisting of myotoxins, cardiotoxins, mellitin, and phospholipases.

62. (new) The formulation of claim 56 wherein the bioactive peptide is selected from the group consisting of protein hormones and enzymes.

63. (new) The formulation of claims 62 wherein the bioactive peptide is a protein hormone selected from the group consisting of oxytocin, arginine vasopressin, insulin, growth hormone and calcitonin.

64. (new) The formulation of claim 62 wherein the bioactive peptide is an enzyme selected from the group consisting of ribonuclease, lysozyme, chymotrypsin, trypsin, elastase, and papain.

65. (new) The formulation of claim 9 wherein the peptide is prepared by a method comprising the step of preparing a cDNA strand encoding the peptide.

66. (new) The formulation of claim 65 wherein the peptide is prepared by expressing the cDNA under conditions in which the peptide is recovered in an inactive form due to the failure to form one or more disulfide bridges.

67. (new) A medicament delivery formulation comprising an effective amount of an inactivated bioactive macromolecule and an effective amount of a mucosal absorption enhancer comprising a quaternary ammonium salt for enhancing mucosal absorption of the peptide.

68. (new) The system of claim 67 wherein the bioactive macromolecule comprises a bioactive peptide having a molecular weight of at least 500 daltons, the quaternary ammonium salt comprises benzalkonium chloride at a final concentration of between about 0.001 % and about 0.1 % based on the weight of the formulation, the bioactive peptide a) has been inactivated by a method comprising the steps of treating the peptide with ozone under conditions suitable to oxidize any disulfide bonds in order to form corresponding pairs of cysteic acid residues, and then stabilizing the resultant cysteic acid residues and preventing the reformation of disulfide bonds, and b) is selected from the group consisting of toxins affecting the presynaptic neurojunction, toxins affecting the postsynaptic neurojunction, toxins affecting ion channels, and toxins that damage the cell membrane.

69. (new) The formulation of claim 68 wherein the benzalkonium chloride is used at a final concentration of about 0.005 % and about 0.05 %, based on the weight of the formulation, the inactivated bioactive peptide retains one or more properties selected from the group consisting of immunogenicity and anti-viral activity, and the bioactive peptide comprises a toxin affecting the postsynaptic neurojunction and is selected from the group consisting of α-conotoxins, α-cobrotoxin, erabutoxin, α-cobratoxin and α-bungarotoxin.

Remarks

Claim 2 has been deleted and claims 1, 3, and 7-9 have been amended. Claims 11 – 69 have been added, antecedent basis therefore existing throughout the application, e.g., at page 6, lines 3-7 (with respect to enhancer concentrations), at page 9, line 20 to page 11, line 18 (with respect to bioactive peptides, including toxins) and at page 6, line 8 to page 7, line 3 (with respect to ozone and cDNA methods of preparing inactivated bioactive peptides).